REMARKS

Claims 22-38 and 56, of which claims 22, 50 and 58 are amended herein, appear in this application for the Examiner's review and consideration. Claims 1-21, 39, 49, and 51-52 have been cancelled. Claim 22 has been amended to clarify the invention by reciting the liner of the printed patch as being "non-adhesive", support for which is found in paragraphs [0105], [0112], [0119] and [0123] of the published application. Claim 50 has been amended to be consistent with the amended claim 22. Claim 58 has been amended to include the phrase "a microporous liner" which was inadvertently deleted in the previous amendment. As no new matter is introduced, entry of the amendments at this time is respectfully requested. It is understood that process and system claims 40-48, 50, 53-55 and 57-79 have been withdrawn from consideration but will be rejoined when the printed patch of method claim 22, from which they directly or indirectly depend, is allowed.

The Specification was objected to by the Examiner for informality. In response, Applicants note that a proper cross-reference section should only refer to earlier US applications and not to foreign priorities. Accordingly, the Specification has not been amended to refer to the prior-filed Israel application IL 152574. Therefore, this objection should be withdrawn.

Claim 22 was rejected under 35 U.S.C. 112, second paragraph, for failing to comply with the written description requirement. In response, Applicants have deleted the phrase "an exposed surface of" from claim 22 to overcome the new matter rejection. Thus, the rejection of claim 22 under 35 U.S.C. 112, second paragraph, should be withdrawn.

Claims 22-25 and 37 were rejected again under 35 U.S.C. 102(b) as being anticipated by U.S. patent No. 5,958,447 to Haralambopoulos et al. (referred to hereafter as "Haralambopoulos"). Haralambopoulos teaches powdered patches wherein an active substance in a powder form becomes incorporated or embedded in the adhesive matrix of a transdermal patch by application of heat and/or pressure.

The Examiner is correct in stating that Haralambopoulos teaches an active substance in a powder form that is sprinkled, deposited or spread on an exposed adhesive surface of a patch. However, unlike in the present invention, the active substance in Haralambopoulos is not maintained on the exposed adhesive surface of the patch since it is then effectively driven by low heat or pressure into the adhesive matrix, where it becomes embedded at a depth just below the

surface of the adhesive matrix as evidenced by the fact that the entire surface area of the adhesive matrix, previously powdered and non-tacky, regains its pressure sensitive adhesive properties (FIGs. 2 and 3, and col. 7 lines 20-25 of Haralambopoulos).

Thus, in Haralambopoulos, the drug-containing layer has adhesive properties. In contrast, in the present invention as recited in the amended claim 22, the claimed printed patch wherein the dried pharmaceutical composition comprising the active agent is placed on a non-adhesive or non-adherent liner. Since this non-adhesive or non-adherent liner where the drug is placed neither has nor regains any adhesive properties, the drug-containing layer in the present application is not adhesive. Therefore, the adhesive properties of the patch of the present invention are not achieved by the drug-containing layer, but rather by an additional adhesive layer. Furthermore, the patch of the present invention is distinct from, and advantageous over, the patch of Haralambopoulos in that it is also suitable for sensitive active materials that are unfit for the drug-containing adhesive type of patch claimed in Haralambopoulos.

Claim 38 was rejected again under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos. As discussed above, the patches disclosed by Haralambopoulos are substantially different from the printed patch of the present invention. Moreover, the printed patch recited in claim 38, wherein the pharmaceutical composition further comprises at least one component selected from an anti-oxidant, a buffering agent and a preservative, is neither taught nor suggested by Haralambopoulos. Therefore, claim 38 is not obvious over Haralambopoulos.

Claims 26, 28-29 and 32-33 were rejected again under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos in view of U.S. patent No. 6,274,166 to Sintov et al. (referred to hereafter as "Sintov"). As explained above, Haralambopoulos teaches transdermal patches for powdered, liquid or semi-liquid pharmaceutical or cosmetic substances, which substances are suitable for topical administration. The active substance exemplified in Haralambopoulos is ascorbic acid. Haralambopoulos does not teach the presently claimed patch structure or the use of insulin as an active agent. Sintov teaches proteins that can be incorporated into adhesive patches but all the examples disclosed by Sintov relate to topical application of insulin in solution on the skin of animals. Thus, it would not be obvious to one of ordinary skill in the art at the time the invention was made to formulate a dried pharmaceutical composition comprising a large molecule such as insulin into a printed patch of the present invention.

Furthermore, since Sintov does not remedy the deficiencies of Haralambopoulos, even if Sintov is combined with Haralambopoulos, one of ordinary skill in the art would not obtain the presently claimed invention. Therefore, claims 26, 28-29 and 32-33 are patentable over this combination of references.

Claims 27, 29 and 32-34 were rejected again under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos in view of US 6,274,582 to Marin (referred to hereafter as "Marin"). As explained above, Haralambopoulos teaches transdermal patches for powdered, liquid or semi-liquid pharmaceutical or cosmetic substances, which substances are suitable for topical administration. The active substance exemplified in Haralambopoulos is ascorbic acid. Haralambopoulos does not teach human growth hormone (hGH) as an active agent. Marin teaches the use of hGH in combination with a cortisol synthesis inhibitor for preventing or treating conditions related to Metabolic Syndrome. Though Marin teaches that the active agents or compositions may be formulated as transdermal patches (col. 5 lines 37-41 of Marin) and the administration may be transdermally (col. 5 lines 48-49 of Marin), hGH was administered by subcutaneous or intramuscular injection in solution in all the examples of Marin (col. 3 lines 56-57 and col. 6 lines 9-13 of Marin). Thus, it would not be obvious to one of ordinary skill in the art at the time the invention was made to formulate a dried pharmaceutical composition comprising a large molecule such as hGH into a printed patch of the present invention. Furthermore, since Marin does not remedy the deficiencies of Haralambopoulos, even if Marin is combined with Haralambopoulos, one of ordinary skill in the art would not obtain the presently claimed invention. Therefore, claims 27, 29 and 32-34 are patentable over this combination of references.

Claim 56 was rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos in view of US 5,611,806 to Jang (referred to hereafter as "Jang"). Haralambopoulos teaches transdermal patches for powdered, liquid or semi-liquid pharmaceutical or cosmetic substances, which substances are suitable for topical administration, but does not teach two electrodes integrated into the patch. Jang teaches Korean patent publication 92-2264 which discloses a patch type device for transdermally delivering insulin to patients (col. 1 line 48 of Jang). The Examiner asserted that the patch type device disclosed by Korean patent publication 92-2264 comprises an insulin solvent reservoir constituting a water

swellable, high molecular, insulin carrying layer on which insulin is dispersed in a powder form, a needle support adapted to expand as the insulin solvent is discharged from the reservoir, and an electrode attached to the ceiling of the reservoir for supplying the reservoir and the bodily skin with electricity (col. 1 lines 50-60 of Jang). Although the patch type device disclosed in Korean patent publication 92-2264 includes an electrode, the electrode is attached to the insulin solvent reservoir. The patch type device disclosed in Korean patent publication 92-2264 further includes a needle support and a multiplicity of skin perforation needles. Thus, it would not be obvious to one of ordinary skill in the art at the time the invention was made to integrate electrodes to a printed patch comprising a dried pharmaceutical composition comprising insulin, wherein the patch is devoid of solvent reservoir and needles. Since Jang does not remedy the deficiencies of Haralambopoulos, even if Jang is combined with Haralambopoulos, one of ordinary skill in the art would not obtain the presently claimed invention. Therefore, claim 56 is patentable over this combination of references.

Claims 22-26, 29-36 and 38 were provisionally rejected for nonstatutory obviousness-type double patenting over the claims of the later filed copending application 11/327,016. It is noted that the provision has not occurred in that application so that this rejection should be withdrawn at this time, since it is holding up the allowance of the present application. Applicant agrees to file a terminal disclaimer in this or the copending application, whichever is found to be allowable later than the other, to avoid any possible obviousness type double patenting issues.

In view of the above, it is believed that the entire application is in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a telephonic or personal interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the claims.

Respectfully submitted,

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